

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Mylan Laboratories Limited, India, submitted in 2020 an application for Pretomanid Tablets 200 mg¹ (TB386) to be assessed with the aim of including Pretomanid Tablets in the list of prequalified medicinal products for treatment of drug-resistant tuberculosis

Pretomanid Tablets was assessed according to the ‘Procedure for Assessing the Acceptability, in Principle, of Pharmaceutical Products for Purchase by United Nations Agencies’ by the team of WHO assessors. The assessors are senior experts, mainly from national authorities, invited by WHO to participate in the prequalification assessment process.

Based on the data submitted the team of assessors advised that Pretomanid Tablets is included in the list of prequalified medicinal products. Pretomanid Tablets was listed on 25 November 2020.

Pretomanid Tablets ‘s conformance to the requirements of the current SRA guideline was re-evaluated by the team of WHO assessors.

2. Steps taken in the re-evaluation of the product

May 2026	WHO letter of request for requalification was sent to the applicant.
July 2026	The application letter was received.
July 2026	The assessment team reviewed the submitted data and further information was requested
August 2026	The applicant’s response letter was received.
September 2026	The submitted data were reviewed and found to comply with the relevant WHO requirements.
16 September 2026	Requirements of requalification were met. Pretomanid Tablets 200 mg remained on the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

Further information is available at:

<https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products>

¹ Trade names are not prequalified by WHO. This is the National Medicines Regulatory Authority’s responsibility. Throughout this WHOPAR the proprietary name is given as an example only.